

REMARKS

Applicant has withdrawn claims 43 and 44 and added new claims 45-50. Support for new claim 47 can be found in original claim 1 and page 3, line 5 of the amended Specification (see the response filed on October 28, 2004). Support for new claims 45, 48, and 49 appears in, e.g., original claim 3 and support for new claims 46 and 50 appears in, e.g., page 2, lines 3-4 of the Specification. Applicant has also corrected deficiencies in claim 11 and the Specification. No new matter has been introduced by the above amendments.

Upon entry of the proposed amendment, claims 1, 11, and 45-50 will be pending and under examination. Reconsideration of the application, as amended, is requested in view of the remarks below.

Rejection under 35 U.S.C. § 103(a)

Claims 1 and 11 are rejected as being obvious over Cheng et al., M. Taiwan J. Med. 3:166-173, 1998 ("Cheng I"), Cheng et al., J. of E.N.T. Medicine, 33:431-441, 1998 ("Cheng II"), Chou et al., China Medical College Journal, 8(1):13-18, 1999 ("Chou"), or Lin, Annual Report of Chinese Medicine Committee, DOH, ROC, 16:79-98, 1998 ("Lin")¹ in view of Huo et al., CN1079150 ("Huo"). See the Office Action, page 2, lines 14-17.

Applicant discusses independent claim 1 first. It covers a nutraceutical composition containing extracts of four herbs: (1) *Hedysarum polybotrys* Hand.-Mazz. or *Astragalus membranaceus* Bge., (2) *Atractylodes macrocephala* kodiz, (3) *Ledebouriella seseloides* (hoffm.) Wolff, and (4) *Flos Magnoliae*. The composition can be used for treating, among others, allergic rhinitis.

As correctly pointed out by the Examiner, "all of [Cheng I, Cheng II, Chou, and Lin] teach that Yu Ping Feng San which comprises Huang qi, Bai Zhu, and Fang Feng (*Astragalus membranaceus*, *Atractylodes macrocephala* kodiz, *Ledebouriella seseloides*) in ratios including 1:1:1 were effective in treating allergic rhinitis (see [the] English Abstracts). None of [these

¹ The information disclosure statement filed on April 29, 2004 erroneously listed "Gin," instead of "Lin," as the name of the sole author of the article designated "AT." In other words, the correct citation for this article should read "Lin, Annual Report of Chinese Medicine Committee, DOH, ROC 16:79-98, 1998. Applicant refers to this article as "Lin" in this response.

four] references specifically taught the incorporation of *Flos Magnoliae* (Magnolia flower) into the composition.” See the Office Action, page 3, lines 1-6.

Huo does not cure this deficiency in these four references. It describes a composition containing eleven ingredients. According to its Chinese specification, “the composition contains Xin Yi Hua [i.e., magnolia flower] 95-105 g, Guang Jiao 80-100 g, Chuang Shan Jia 38-42 g, She Xiang 70-78 g, Bai Zhi 39-41 g, Gu Fan 100-120 g, Wu Bei Zi 100-130 g, Fang Feng 45-55 g, Cang Er Zi 95-110 g, Jin Yin Hua 38-42 g, Pi Pa Ye 49-51 g.” See page 2, first paragraph of Huo, a copy of which is attached hereto as “Exhibit A.”² The composition can be used for treating eight diseases, i.e., acute rhinitis, nasal congestion, conchitis, nasosinusitis, sinusitis, maxillary sinusitis, rhinopolyp, and allergic rhinitis. See the Abstract. However, Huo does not teach or suggest a composition containing a combination of Huang Qi, Bai Zhu, Fang Feng, and magnolia flower, as required by claim 1.

The Examiner contends that “it would have been obvious to one of ordinary skill in the art at the time of the claimed invention was made to combine the instant ingredient for their known benefit since each is well known in the art for treating allergic rhinitis.” See the Office Action, page 3, lines 9-12. Applicant disagrees. Huo describes a composition containing eleven ingredients for treating eight diseases. It is unclear to one skilled in the art which ingredient in the composition is effective in treating which disease. Indeed, the probability of picking magnolia flower from ten ingredients (excluding Fang Feng which is already recited in claim 1) for treating allergic rhinitis selected from eight diseases is only 1/80 ($1/10 \times 8 = 1/80$), i.e., 1.25%. Given this low probability, one skilled in the art, in view of Huo, would not have been motivated to combine magnolia flower with Huang Qi, Bai Zhu, and Fang Feng to prepare a composition of claim 1 for treating allergic rhinitis. In sum, all the Examiner has done is, with the benefit of the knowledge of this invention, picking and choosing four ingredients (three described in Cheng I, Cheng II, Chou, and Lin and one described in Huo) and then combining them to arrive at the composition of claim 1 even though the cited references do not suggest in any way such a combination.

² Applicant's counsel is proficient in both English and Chinese and verifies that the translation is complete and accurate.

For the reasons set forth above, claim 1 is not obvious over Cheng I, Cheng II, Chou, and Lin in view of Huo. Neither is claim 11, which depends from claim 1.

New claims

Applicant submits that new claims 45-50 are novel and non-obvious over Cheng I, Cheng II, Chou, Lin, and Huo.

Claims 45 and 46 depend from claim 1. As discussed above, none of Cheng I, Cheng II, Chou, Lin, and Huo teaches or suggests the composition of claim 1. It follows that these references also do not teach or suggest the composition of claims 45 and 46. Thus, claims 45 and 46 are also novel and nonobvious over these references.

Claim 47 covers a nutraceutical composition containing extracts of three herbs: (1) *Atractylodes macrocephala kodiz* (i.e., Bai Zhu) (2) *Ledebouriella seseloides (hoffm.) Wolff* (i.e., Fang Feng), and (3) *Flos Magnoliae*. In other words, the nutraceutical composition contains the second, third, and fourth herbs recited in claim 1.

As pointed out above, Cheng I, Cheng II, Chou, and Lin describe a composition containing Huang Qi, Bai Zhu, and Fang Feng. None of these references teaches or suggests a composition containing *Flos Magnoliae*. As also pointed out above, Huo describes using a composition containing eleven ingredients (including magnolia flower) to treat eight diseases. The probability of picking magnolia flower for treating allergic rhinitis is only 1.25%. See the discussion, *supra*. Given this low probability, one skilled in the art, in view of Huo, would not have been motivated to combine magnolia flower mentioned in Huo with Huang Qi, Bai Zhu, and Fang Feng mentioned in Cheng I, Cheng II, Chou, and Lin to prepare the composition of claim 47. Thus, claim 47 is novel and non-obvious over Cheng I, Cheng II, Chou, Lin, and Huo. Neither are claims 48-50, all of which depend from claim 47.

CONCLUSION

Applicant submits that the grounds for rejection asserted by the Examiner have been overcome, and that claims 1, 11, and 45-50, as pending, define subject matter that is novel and nonobvious. On this basis, it is respectfully submitted that all of the pending claims are now in condition for allowance, an action of which is requested.

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Respectfully submitted,

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[54] 发明名称 中药鼻炎注射剂的制作方法

[57] 摘要

中药鼻炎注射剂的制作方法。治疗急性鼻炎,因六淫和鼻功能失调所引起的鼻塞、鼻甲肥大、鼻窦炎、副鼻窦炎、上颌窦炎和多发性鼻息肉及过敏性鼻炎等症。本药针剂,其特征含有:辛夷花、痰角、穿山甲、麝香、白芷、枯矾等药。制作工艺简单,功能排脓解毒,软坚散结、活血去瘀,用药方便,疗程短,疗效快,不用开刀、无副作用,有效率达 99%,治愈率达 95%以上。

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权 利 要 求 书

1. 中药鼻炎注射剂的制作方法, 其特征在于: 其配方含有辛夷花95-105g, 广角80-100g, 穿山甲38-42g, 射香70-78g, 白芷39-41g, 枯矾100-120g, 五倍子100-130g, 防风45-55g, 苍耳子95-110g, 金银花38-42g, 枇杷叶49-51g等中药配制而成。

- (1) 将广角用热水浸泡捞出晒干、打碎、研粉备用。
- (2) 将穿山甲置砂锅内炒至金黄色, 取出筛出砂子, 立即倒入醋盆内搅拌略浸, 捞出漂洗晒干、打碎、研粉务备用。
- (3) 将白芷洗净, 以10%的石灰水搅拌均、晒干、打碎备用。
- (4) 将射香研成极细的粉末于120目过筛细末备用。
- (5) 辛夷花, 拣净梗、枝及杂质捣碎备用。
- (6) 枯矾, 取净白矾置砂锅内加热煨至枯干研粉备用。
- (7) 五倍子, 拣净敲开去杂质打碎备用。
- (8) 防风去残茎, 从温水中捞出润透切片晒干打碎备用。
- (9) 苍耳子, 拣出杂质去刺筛去灰屑, 微炒黄色, 取出放凉, 打碎备用。
- (10) 金银花, 将拣净金银花置锅内炒至焦褐色, 喷清水, 晒干, 打碎备用。
- (11) 将枇杷叶, 刷去绒毛洗净, 切丝, 晒干备用。
- (12) 首先将称量好的广角、穿山甲用五升水同时放入10升不锈钢器皿内, 用火煎至180分钟的药液, 再放入辛夷花、苍耳子、枇杷叶、防风、五倍子、枯矾、金银花加水3升, 同煎120分钟, 过滤去渣的滤液, 在滤液中再加入白芷同煎至700毫升药液过滤去渣剩药液500毫升。

在药液内加入75% 的酒精250g搅均使之再度提取有效成份后置1000毫升的玻璃器皿内煎至510毫升时,再加入射香和活性碳1g,急搅约5分钟后出火倒入已消毒好的不锈钢器皿内封严至冷却后,先用滤纸过滤,再用聚乙烯微孔薄膜负压过滤后至无菌操作台上装入无菌的1毫升安瓶内即封口,合计每料成品500支。

将封口好安瓶药液放至高压消毒柜中用1.5大气压和120℃高温进行1.5小时消毒取出,包装,注意避光保存,有效期2年。

中 药 鼻 炎 注 射 剂 的 制 作 方 法

本发明是属于一种治疗鼻炎症中药针剂的制作方法。

目前市场上治疗鼻炎的方法，大多都采用口服中成药。用药时间长，效果不够显著。本发明的中药针剂，对于治疗急、慢性鼻炎，因六淫和鼻功能失调所引起的鼻塞、鼻甲肥大、鼻窦炎、付鼻窦炎、上颌窦炎和多发性鼻息肉、过敏性鼻炎等症。用本药针剂，排浓解毒，软坚散结，活血化瘀，疗程短，疗效快，治愈率高。

参考文献

(1) 《普济方》第二册，身形篇五十六卷鼻门总论 <人民卫生出版社出版，1982年第一版第三次印刷>，作者：明朝朱棣田等编。

(2) 《东医宝鉴》外形编卷二鼻门 <人民卫生出版社出版，1982年 第一版印刷> 作者 朝鲜，许浚。

(3) 《赤水玄珠》第三卷鼻门，鼻息肉，鼻渊篇<人民卫生出版社，1986年 第一版印刷>，作者 明朝 孙一奎。

(4) 《本草纲目》1982年11月第一版印刷 作者 明朝 李时珍。

(5) 《景岳全书》二十七卷，杂证谈，鼻病篇<上海科学技术出版社，1984年，第五次印刷>，作者 孙介宾。

(6) 《耳鼻咽喉科学》第三篇，鼻部疾病<中国人民解放军总后勤部卫生部，南京军区军医学校主篇，1980年12月第一版印刷。

本发明的目的在于研制成对急、慢性鼻炎、鼻窦炎、 过敏性鼻炎

炎、鼻息肉等症；能解除鼻炎患者的头痛，鼻塞的病痛，不用开刀，无毒、无副作用，疗程短，疗效快，治愈率高达95%以上的一种中药鼻炎注射剂的制作方法。

本发明的中药鼻炎注射剂的制作方法，其配方含有：辛夷花95-105g，广角80-100g，穿山甲38-42g，射香70-78g，白芷39-41g，枯矾100-120g，五倍子100-130g，防风45-55g，苍耳子95-110g，金银花38-42g，枇杷叶49-51g等中药配制而成。

(1) 将广角用热水浸泡捞出晒干、打碎、研粉备用。

(2) 将穿山甲置砂锅内炒至金黄色，取出筛出砂子，立即倒入醋盆内搅拌略浸，捞出漂洗晒干、打碎、研粉备用。

(3) 将白芷洗净，以10%的石灰水搅拌均、晒干、打碎备用。

(4) 将射香研成极细的粉末于120目过筛细末备用。

(5) 辛夷花，拣净梗、枝及杂质捣碎备用。

(6) 枯矾，取净白矾置砂锅内加热煨至枯干研粉备用。

(7) 五倍子，拣净敲开去杂质打碎备用。

(8) 防风去残茎，从温水中捞出润透切片、晒干、打碎备用。

(9) 苍耳子，拣出杂质去刺、筛去灰屑，微炒黄色，取出放凉，打碎备用。

(10) 金银花，将拣净金银花置锅内炒至焦褐色，喷清水，晒干，打碎备用。

(11) 将枇杷叶，刷去绒毛洗净，切丝，晒干备用。

(12) 首先将称量好的广角、穿山甲用水五升同时放入10升不锈钢器皿内，用火煎至180分钟的药液，再放入辛夷花、苍耳子、枇杷叶、防风、五倍子、枯矾、金银花加水3升，同煎120分钟，过滤去

渣的滤液，在滤液中再加入白芷同煎至700毫升药液过滤去渣剩药液500毫升。

在药液内加入75%的酒精250g搅均使之再度提取有效成份后置1000毫升的玻璃器皿内煎至510毫升时，再加入射香和活性碳1g，急搅约5分钟后出火倒入已消毒好的不锈钢器皿内封严至冷却后，先用滤纸过滤，再用聚乙烯微孔薄膜负压过滤后至无菌操作台上装入无菌的1毫升安瓶内即封口，合计每料成品500支。

将封口好安瓶药液放至高压消毒柜中用1.5大气压和120℃高温进行1.5小时消毒取出，包装，注意避光保存，有效期2年。

本中药鼻炎注射剂是针对因风、寒、暑、湿、燥、火侵入鼻窦大脑所引起的经常感冒而导致的各种急、慢性鼻炎、鼻塞、鼻甲肥大、过敏性鼻炎、付鼻窦炎、上颌窦炎及经常感冒、头痛、流清脓涕和多发性鼻息肉等各种鼻炎症状，将本注射剂直接注射到下鼻甲和息肉患部，将病毒自动排出，然后自动吸水，一般八天左右见效，一个月左右全愈，每次注射1毫升，连续注射3天，每天一次，不用开刀，不影响工作，无毒付作用。

注：《本针剂对萎缩性鼻炎无效》禁忌：高血压、心脏病、孕妇、禁用。

本发明的优点：发明人用十几年的时间，查大量中草药资料，从国内外传统中医学药物中优选多种方鉴，进行许多点型病例试验之后鉴定的处方，同时又研制成针剂，使用方便，便于治疗，疗程短、疗效快，本药无毒、无副作用，用药安全，解毒排脓，软坚散结、活血去瘀。有效率99%，治愈率高达95%以上。

病例1：万新生，男，33岁，武昌区粮食局第四中心粮店司机。病史：

患多发性鼻息肉，鼻甲肥大，过敏性鼻炎。经常鼻塞、头痛，流清水涕，打喷嚏，鼻腔发痒，易感冒，15年左右，经开刀和各方面治疗，症状没有缓解。于91年8月2日来我处治疗，用鼻炎注射液每天注射一次（1毫升），连续注射三天后观察一星期，而患者上述所有症状消失，经一个月后复查已达痊愈，至今随访设有复发。

病例2：程汉林，男，30岁，武汉市洪山规划土地管理处。病史：患鼻甲肥大，付鼻窦炎10多年左右，经常鼻塞，头痛，脓涕多，经治疗效果不佳，于91年7月8日来我处治疗，用本注射液连续注射3天后，一星期观察上面症状开始好转，经一个月左右复查，头痛、脓涕消失，还有轻微鼻塞，后又用本注射液，注射一次，一星期后观察，鼻塞症状全部消失，再1个月后复查已痊愈。

病例3：毛先礼，男，45岁，武昌县郑店工商所（湖北）。病史：患多发性鼻息肉，付鼻窦炎、上颌窦炎、鼻甲肥大20年左右。经常鼻塞，头痛，脓涕多，经3次开刀和多方面治疗无效，于91年7月15日到我处治疗用鼻炎注射液每10天注射1次（每次1毫升）经4次注射后，付鼻窦炎、上颌窦炎、鼻甲肥大基本痊愈，还有少量息肉和脓涕，后继续10天注射一次，经6次注射上述药液，症状全部消失，至92年5月复查已痊愈没有复发。

病例4：周理敬，男，42岁，郑州铁路局，武汉铁路分局计划统计科。病史：患鼻甲肥大，过敏性鼻炎，约二年左右，经常鼻塞，流清水涕，打喷嚏，发痒，经多方面治疗均无效，于91年9月15日到我处治疗，用鼻炎注射液连续注射3天（每次1毫升）注射后第2天打喷嚏、发痒消失，1个月左右复查上面症状已痊愈。随访至今没有复发。

病例5：曾海珍，女，41岁，武汉冶炼厂工人。病史：患鼻肥大，

32年左右经常头痛,头昏,眼痛,鼻腔发干,鼻塞,经多方面治疗无效,于91年9月28日到我处治疗,用鼻炎注射液连续注射3天,一星期后观察,头痛、眼痛、头昏、鼻塞消失,鼻腔发干无明显好转;一个月左右,再用注射液注射一次,半个月后复查已痊愈,至今随访无复发。

注:每次注射双鼻腔,每次1毫升即可。

最佳实施例:

中药鼻炎注射剂的制作方法

- (1) 首先将獐角80g,用热水浸泡捞出晒干打碎研粉备用。
- (2) 穿山甲100g,置砂锅内炒至金色,筛出砂子取出,立即倒入醋盆内搅拌略浸,捞出漂洗晒干打碎研粉备用。
- (3) 将白芷40g,洗净,以10%的石灰水搅拌均匀晒干打碎备用。
- (4) 将射香70g,研极细粉末于120目过筛的细末备用。
- (5) 辛夷花100g,拣净梗、枝及杂质,捣碎备用。
- (6) 枯矾100g,取净白矾置砂锅内加热煅至枯干研粉备用。
- (7) 五倍子100g,拣净敲开、去杂质、打碎备用。
- (8) 防风50g,去残茎从温水中捞出润透切片晒干,打碎备用。
- (9) 苍耳子100g,拣出杂子,去刺筛去灰屑,微炒黄色取出放凉,打碎备用。
- (10) 金钹花40g,将拣净金银花后好置锅内炒至焦褐色,喷清水晒干,打碎备用。
- (11) 枇杷叶50g,刷去绒毛,洗净切丝晒干备用。
- (12) 先将獐角、穿山甲放入10升不锈钢器皿内煎至180分钟同水5升,再放入辛夷花、苍耳子、枇杷叶、防风、五倍子、枯矾、金钹花加水3升同煎120分钟后过滤去渣、在滤清液内加入白芷同煎至700毫

升药渣后过滤去渣,剩药液500毫升。

在药液内加入75%的酒精 250g 搅匀使之再度提取有效成份后置1000毫升的玻璃器皿内煎至510毫升时加入射香和活性碳1g 急搅约5分钟后出火倒入已消毒的不锈钢器皿内封严至冷却后先用滤纸过滤,过滤后再用聚乙烯微孔薄膜负压过滤后至无菌操作台上装入1毫升灭菌安瓶内即封口合计每料成品500支。

将封口好的药物安瓶,放至高压消毒柜中,用1.5大气压和120℃高温进行1.5小时消毒、取出包装,注意避光保存,有效期二年。

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